

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

JAN 1 1 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Lewis Ward Cerol International, LLC 6120 E. 58th Avenue Commerce City, CO 80022

Subject:

OMC II Spray

EPA Registration Number: 46851-5 Application Date: October 6, 2009 Receipt Date: October 13, 2009

Dear Mr. Ward:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment:

Label Amendment

Conditions

Revise your label as follows:

- 1) The second statement in "For Disinfection" directions, the "Disposal of Infectious Materials" statement under the HIV directions, and must be brought into compliance with PR Notice 2000-5. Mandatory Labeling, by deleting the term, should, and stating "must."
- 2) Revise the "Disinfection" directions the statement, "allow surfaces to remain wet..." to read "allow surfaces to remain wet for 10 minutes and allow to air dry."
- 3) Since this product is for use in veterinary clinics, you must add the following directions in accordance with DIS/TSS 18:

Remove all animal and feed from premises and closures. Remove litter and manure from floors. walls, surfaces of cages, and other facilities and fixtures occupied or traversed by animals. Empty at feed and watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water. Saturate all surfaces with OMC II Spray for a period of 10 minutes. Immerse halters, collars, leashes, and other types of equipment used in handling and restraining animals as well as forks. shovels, and scrapers used to remove litter and manure. Ventilate buildings, cars, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feeding and watering equipment with soap or detergent, and rinse with potable water before reuse.

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DATE					*************			
ลายหมูทธ	ter the Ingred	ients Statem	ents, add the	statement, "K	EEP OUT OF	REACH OF	CHILDREN."	-
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will in compliance with PR Notice 2000 5. Mandator Laborita.								
4) Delete the term "Recommended" from the second claim under the "Broduct Name" such that it								

- 7) Add the signal word, "CAUTION" to the center panel. It must appear after the Keep out of reach of children statement.
- 6) Revise the subheading, "User Safety Recommendations" to read "User Safety Instructions." Also. revise the statements in this section be in compliance with Mandatory Labeling to delete the term. should, and stating "must."

General Comments:

A copy of the stamped accepted label with conditions is enclosed. Submit three (3) copies of vour final printed labeling before distributing or selling the product bearing the revised labeling.

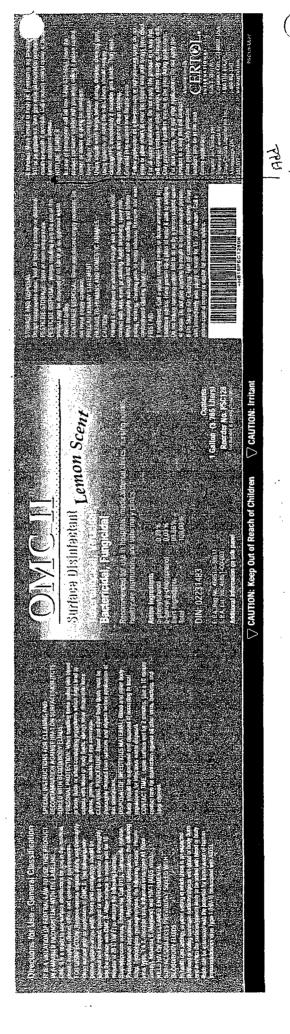
Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 or by email at swift killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely

acqueline McFarlane

(Acting) Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure: Stamped Label



contact lenses, if present, after the first 5 minutes, then continue rinsing Lâll a Pôisôn Control If in eyes: Hold eye open and rinse slowly and gently with water 15-20 minutes. Remove Center or doctor for treatment advice.

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